

The Examiner has further asserted that claims 3, 6 and 7 are indefinite because it is not clear how the total diet of a human can be calculated accurately. Claim 3 has now been amended to recite that the composition contains an amount of between about 200 to about 600 IU per kilogram of body weight. See the specification at page 6, lines 1-2. Claims 6 and 7 have been cancelled. The language of amended claim 3 is believed to be definite and complies with the statute.

The Examiner asserts that claim 9 is indefinite because it is not clear what types of protein would be considered "crude." However, the term "crude protein" is believed to be well known and understood in this art. See the enclosed copies of documents obtained from the Internet which show the known calculation of crude protein in animal food and the fact that the term references a known standard. One skilled in the art would certainly know what is meant by this term.

The Examiner has also asserted that the term "total" dietary fiber is confusing. Again, applicants submit that this term is well understood by those skilled in the art. Further, the term "total dietary fiber" is clearly defined in co-pending application serial No. 09/055,538, which is incorporated by reference in the present application (page 6, line 28). That application has now matured into U.S. Patent No. 5,932,258, issued August 3, 1999 (see amended specification). Accordingly, claims 1-5 and 9 are believed to be in compliance with §112, second paragraph.

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,714,472 to Gray et al. Gray et al. teach a nutritional formulation for intensive care patients which comprises a protein source, a lipid source, and a carbohydrate source. The Examiner refers to Formula Example 3, which discloses a nutrient composition which "may have" a "nutrient profile" which includes Vitamin A, L-carnitine, and chromium. While the Examiner acknowledges that Gray et al. do not teach that their composition promotes weight loss, she has taken the position that the ingredients "are identical to the ingredients in the claimed invention" and that Gray's composition would inherently have the same weight loss effect as the claimed invention. However, Gray's composition is designed to provide a high caloric content. See col.

3, lines 48-56. Accordingly, it is not believed that Gray's composition would inherently provide weight loss.

Further, there is no teaching in Gray et al. of using the **specific combination** of L-carnitine, chromium, Vitamin A and a low glycemic index grain as recited in claim 1 as amended. Rather, these components are included along with a number of other vitamins and minerals and are shown as an example of one possible nutrient profile for use in the product.

Accordingly, Gray et al.'s **general** teaching of a **high calorie** nutritional formulation for intensive care patients which may include the claimed components does not anticipate the **specific** claimed combination of L-carnitine, chromium, and Vitamin A in a composition for promoting **weight loss**.

Claims 1, 2 and 8 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,104,677 to Behr et al. Behr et al. teach a liquid nutritional product for critical care patients comprising a fat source and dietary fiber. The Examiner has referred to Table XV, which discloses a nutrient profile which may include carnitine, chromium, Vitamin A, and dietary fiber. The Examiner again asserts that Behr's composition would inherently have the effect of promoting weight loss. However, Behr et al. are also directed to a high calorie formulation. See Table XV which discloses a preferred calorie content of 245 to 255 Kcal per serving. Behr et al. would clearly not inherently provide weight loss.

Further, there is no teaching in Behr of using the **specific combination** of L-carnitine, chromium, Vitamin A and a low glycemic index grain for the purpose of achieving **weight loss**.

Claims 1-9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,849 to Hastings, the Purina CNM Veterinary Product Guide (1994) and U.S. Patent No. 5,240,962 to Nakatsu et al. Hastings teaches a dietary supplement for promoting weight loss in humans which contains chromium and L-carnitine. The Purina Product Guide teaches a weight loss diet for dogs which includes high fiber and which may include vitamin supplements including vitamin A. Nakatsu et al. teach a weight loss composition for animals

including alkyl or alkenyl phenols which are administered by mixing with the animal's feed which may include grains.

The Examiner opines that the compositions disclosed in the references are all used in weight loss compositions and that one of ordinary skill in the art would have a reasonable expectation that a combination of the specific claimed substances, namely, chromium, L-carnitine, Vitamin A, corn, sorghum, and barley would be combinable into a single composition. Applicants disagree. While the Examiner asserts that Nakatsu et al. teach the use of corn, sorghum, and barley grains "in a weight loss regimen", the grains are clearly taught for the purpose of mixing with the active compound for administration to the animal. See col. 5, lines 31-40. There is no teaching or suggestion in Nakatsu that such grains are directly related to weight loss. Thus, there would be no expectation that such grains would function effectively in combination with the other claimed substances to provide a composition for promoting weight loss.

Nor is there any specific teaching in the Purina Product Guide of the inclusion of vitamin A in a weight loss diet. Rather, the guide teaches a composition which, in its dry form, may include vitamin supplements such as Vitamin A. Applicants note that the canned ingredients do not include vitamin A (see page 17). Nothing in the Purina Product Guide teaches or suggests that Vitamin A provides any weight loss benefits.

Accordingly, there is no motivation for one skilled in the art to pick and choose specific components from a dietary supplement for humans (Hastings) and combine them with a high fiber diet for dogs (Purina) which may or may not contain vitamin A. Nor would one look to the teachings of Nakatsu, who do not teach the use of a low glycemic index grain to promote weight loss.

While none of the references teach or suggest combining the components in the dosages claimed, the Examiner has taken the position that it would have been obvious for one skilled in the art to determine the optimum amount of each component. However, as pointed above, there is no teaching or suggestion in the references which would motivate one to combine their

teachings to form the specific weight loss composition. Nor is there any teaching in the references which would provide guidance as to the determination of amounts which would function effectively as a composition for promoting weight loss.

With this amendment, applicants have added new claim 14 which is also believed to be patentable over the cited references. None of the references teach or suggest the claimed amount of Vitamin A. Behr et al. teach an amount of 1000 to 1500 IU per serving and Gray et al. teach an amount of 1500 IU per serving, both of which are significantly lower than the claimed range of 200 to 600 IU per kilogram of body weight.

For all of the above reasons, applicants submit that claims 1, 3, 4-5 and 8-9 as amended, and new claim 14 are patentable over the cited art of record. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE SPECIFICATION

Page 5, lines 1-7:

Further, mammals fed a carnitine-supplemented diet exhibit a greater percentage of lean body mass (LBM) than mammals fed the same diet, but with no carnitine supplementation. Also, mammals fed a carnitine-supplemented diet voluntarily restrict their food intake. Reference is also made to [co-pending] commonly-assigned U.S. Patent [Application Serial] No. 6,204,291, [09/337,938, filed June 22, 1999, and] entitled PROCESS AND PRODUCT FOR PROMOTING WEIGHT LOSS IN OVERWEIGHT DOGS, the entire contents of which are hereby incorporated by reference.

Page 6, lines 10-30:

The present invention also preferably includes a source of carbohydrates from a low glycemic index grain. Glycemic index is a measure of the rate at which carbohydrates are broken down into glucose and absorbed by the bloodstream. Glycemic index is a relative scale measured from a reference standard food (normally 50 gm white bread = 100). By "low glycemic index" it is meant that the starch source provides a glycemic response which is closer to fasting glucose and insulin levels than a reference standard carbohydrate source. Suitable low glycemic index grains include sorghum, barley, corn, and blends thereof. Brewer's rice is not a suitable grain source for the present invention. The invention may also use multiple grains comprising a blend of sorghum and barley; a blend of corn and barley; a blend of corn and sorghum; or a blend of corn, sorghum, and barley. Preferably, the weight ratio of grain sources in any blends is from about 1:5 to about 5:1, and more preferably the weight ratio of any blends contains substantially equal amounts of each grain (i.e., a 1:1 ratio). Where a combination of three grain sources is used, the weight ratios of the lowest to highest

amount of grain source will vary between from about 1:1 to about 5:1. The composition of the present invention includes an amount of these starch sources to provide a mammal with from about 1.0 to about 3.0 grams of starch per kilogram of body weight per day. Reference is also made to [co-pending] commonly-assigned U.S. Patent [Application Serial Nos. 09/055,538, filed April 6, 1998, and] No. 5,932,258 entitled COMPOSITION AND PROCESS FOR IMPROVING GLUCOSE METABOLISM IN COMPANION ANIMALS, and U.S. Patent Application Serial No. 60/121,087, filed February 23, 1999, and titled ALTERATION OF GLUCOSE METABOLISM IN

IN THE CLAIMS

1.(Amended) A composition for promoting weight loss in a mammal comprising effective amounts of [at least three nutrients selected from the group consisting of] L-carnitine, chromium, Vitamin A, and a source of carbohydrates selected from a low glycemic index grain.

3.(Amended) The composition of claim 1 comprising from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms of chromium, and from about [50,000 IU to about 1,000,000 IU] 200 to about 600 IU of Vitamin A per kilogram of [diet] body weight.